UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	
v.	**No. 4:20-cr-40021-MRG-1**
RAHIM SHAFA	

DEFENDANT'S RESPONSE TO GOVERNMENT'S MEMORANDUM OF LAW IN SUPPORT OF APPLICATION OF THE FRAUD GUIDELINE

Defendant Rahim Shafa, through his counsel, respectfully submits this Response to the government's Memorandum of Law in Support of Application of the Fraud Guideline as Set Forth in the Presentence Investigation Report.

I. THE SENTENCING COMMISSION'S ADOPTED AMENDMENT REGARDING ACQUITTED CONDUCT PRECLDUES APPLICATION OF THE FRAUD CROSS-REFERENCE HERE.

The government's sentencing argument proceeds as if the acquitted conduct Amendment to the sentencing guidelines did not exist. It takes the position that, under the Amendment, "in determining the Guidelines, the Court should ***consider all conduct that is relevant conduct*** for the offenses of conviction." Dkt. 251 at 5 (emphasis added). The government's reading of the Amendment directly contradicts the Sentencing Commission's express purpose "***to exclude acquitted conduct from the scope of relevant conduct*** used in calculating a sentence range under the federal guidelines." Amendments to the Sentencing Guidelines at 2 ("Amendment") (emphasis added).[1] The government's

[1] *Available at* https://www.ussc.gov/sites/default/files/pdf/amendment-process/official-text-amendments/202405_Amendments.pdf

reading and the Sentencing Commission's commentary are directly contradictory and irreconcilable.

The government does not engage at all with the text of the exception allowing for consideration of only that acquitted conduct which "***establishes***, in whole or in part, the instant offense of conviction." Amendment at 1 (emphasis added). Instead, the government appears to advocate for a broader exception, strikingly similar to that proposed by the DOJ during the public comment period and ultimately rejected by the Sentencing Commission. *See* Dkt. 250 at 5 (discussing proposal to allow consideration of acquitted conduct that "***relates***, in whole or in part, to the instant offense of conviction" (citation omitted)). As the defense argued in a prior filing, and the government does not dispute, courts have held in other guidelines contexts that a defendant's conduct establishes an offense only when the conduct, here fraud, proves the elements of the offense, here misbranding. *See* Dkt. 250 at 5-6 (citing cases). The government makes no effort to explain how Dr. Shafa's alleged fraud establishes the elements of his misbranding conviction, because it cannot. This fact alone should preclude application of the fraud cross-reference.

The government's leading authority on this issue, *United States v. Kumar*, No. 23-1087, 2024 WL 3755360 (Aug. 12, 2024), is inapposite. There, the defendant "pled guilty to all three counts" against him, so acquitted conduct was clearly not at issue. *Id.* at *1. The government's only other authority is an out-of-circuit district court opinion that predated the Amendment by ten years. *See United States v. Sen*, 24 F. Supp. 3d 732 (E.D. Tenn. 2014). It represents how courts applied general relevant conduct rules prior to any restrictions on the consideration of acquitted conduct—but it provides no insight

whatsoever regarding application of the Amendment, expressly intended "to exclude acquitted conduct from the scope of relevant conduct used in calculating a sentence range." Amendment at 2.[2]

The smuggling guideline that the government relies upon as a purportedly "independent[]" means of arriving at the fraud enhancement does not, in fact, contain any cross-reference to the fraud guideline. There is an obvious reason for the Sentencing Commission's omission of a fraud cross-reference in this context: deception is inherent in the very nature of the smuggling offense. *See United States v. Montano*, 250 F.3d 709, 715 (9th Cir. 2001) ("Smuggling, by its nature, involves active steps to avoid detection."). If every mislabeled shipment could support application of the fraud guideline, U.S.S.G. § 2B1.1 would govern the vast majority of sentences for defendants convicted of smuggling, effectively displacing the framework erected by the Sentencing Commission for that specific context, which is driven in the first instance by tax loss. *See* U.S.S.G. § 2T3.1.

Instead, the alleged cross-reference relied upon by the government is to the misbranding guideline, U.S.S.G. § 2N2.1, which in turn includes the disputed fraud cross-reference. ***The only guideline at issue here that includes a fraud cross-reference is the misbranding guideline***. Thus, the only way to enhance Dr. Shafa's sentence for fraud is through the misbranding guideline. The Amendment prohibits the government

[2] The evidence of fraud in *Sen* was, moreover, much stronger than that at issue here. The defendant "instructed . . . nurses to administer . . . unapproved drugs" and "submitted claims for reimbursement to health care benefit programs for reimbursement for the FDA approved version of the drug with knowledge, or at least deliberate indifference, that the practice could not be reimbursed for use of unapproved drugs." 24 F. Supp. 3d at 745. Here, by contrast, Dr. Shafa frankly informed patients that the pellet implants were not FDA approved and would not be covered by insurance.

from relying upon conduct underlying its allegation of felony misbranding, which the jury squarely rejected, in order to enhance Dr. Shafa's sentence under the misbranding guideline.

It bears repeating that the government directly pitched its customs-fraud theory to the jury not once but twice in an unsuccessful effort to obtain a conviction on Count Nine charging felony misbranding and Count Five charging conspiracy to defraud the United States. *See* Dkt. 250 at 3. The government paradoxically takes the position that this is nonetheless "*convicted* conduct—not acquitted conduct." Dkt. 251 at 14. That is not so. The Court instructed the jury that an importation could be found to be "contrary to law," sufficient to support conviction on Counts Six through Eight, if the products were misbranded, because they lacked information regarding "the name and place of the business, manufacturer, packer or distributor," "adequate directions for use," and/or the symbol "Rx only." *See* Feb. 8, 2024 Tr. 116. Given the jury's direct rejection of the government's allegations of customs fraud in connection with Count Five, the defense respectfully submits that the government is wrong to simply assume that Dr. Shafa's convictions for unlawful importation were based on a finding that he defrauded customs. The conspiracy to defraud charged there overlapped with the three substantive unlawful importation counts, but crucially added the element of intent to defraud. Just as it did in Count Nine, the jury declined to find that Dr. Shafa acted with such intent. In sum, the alleged customs fraud is not "convicted conduct," but instead (twice) acquitted conduct excluded from consideration by the Amendment.

Kumar, again, involved no acquitted conduct, so it raised no similar issue. And, contrary to the government's suggestion, the First Circuit in that case did not so much as

mention, much less rely upon, any allegedly fraudulent statements to customs in affirming application of the fraud cross-reference. To the contrary, the defendant argued on appeal that the relevant conduct did not involve fraud by "focusing on the discrete act of importation." 2024 WL 3755360, at *4. The First Circuit rejected that argument because the defendant "did not plead guilty to *smuggling* misbranded drugs . . . – he pled guilty to c*onspiring* to smuggle such drugs. . . . Thus, even if [the defendant] [was] correct that the fraudulent statements made by representatives at the call centers . . . were not directly connected to the importation of the pills, they were sufficiently connected to the conspiracy that [he] engaged in to qualify as relevant conduct." *Id.* Here, Dr. Shafa was acquitted of the conspiracy charge but convicted on three standalone substantive counts of smuggling. *Kumar* is readily distinguishable on this basis.

II. FINANCIAL LOSS TO PATIENTS OR CUSTOMS.

The law is clear that a defendant's "gain" from an offense is generally not an appropriate measure of loss. U.S.S.G. § 2B1.1 n.3(B). Notwithstanding this fact, the government persists in calculating the alleged loss as Dr. Shafa's "proceeds from selling the smuggled implants and injections over a period of 2013-2018." Dkt. 251 at 15; *see also id.* at 16 (arguing for loss calculation based on Dr. Shafa's "financial gain from selling goods and providing services stemming from items that never should have entered the country in the first place"). The government's calculation is flawed in several additional respects.

As an initial matter, a cursory review of the supporting document offered by the government belies its own characterization. The very first page includes a payment dated 9/10/2023, more than two years after Dr. Shafa was indicted. *See* Dkt. 251-2 at 2 (11

lines from bottom). There are also many thousands of dollars of entries pre-dating 2013. *See, e.g.*, *id.* at 10 (reflecting $21,525 in payments from 2004 through 2012 on this page alone).

More fundamentally, in order for the amount paid by patients to be a permissible measure of "loss" under § 2B1.1, the government would have to prove that such patients suffered a financial loss proximately caused by the misrepresentations at issue. In other words, it would have to show that Dr. Shafa made material misrepresentations to patients that went "to the essence of the bargain." Dkt. 250 at 12 (quoting *United States v. Arif*, 897 F.3d 1, 10 (1st Cir. 2018)); *see also, e.g.*, *Ciminelli v. United States*, 598 U.S. 306, 312 (2023). For all of the reasons set forth in its prior filings, the defense contends that the government has failed to satisfy its burden of proof on this issue.

Despite the government's efforts to suggest otherwise, naltrexone is widely recognized as an effective treatment for opioid addiction. It is an ingredient in two FDA approved products, one in a tablet form and the other an injection. *See* Feb. 2, 2024 Tr. 41-42. As Dr. Shafa made clear to patients, pellet implants containing naltrexone are not, however, FDA approved.[3] But that fact does not foreclose the possibility of naltrexone implants being a safe and effective treatment for certain patients. The Columbia University Department of Surgery, for example, touts the use of naltrexone implants as "extremely effective." *Naltrexone Implant a Powerful New Tool in the Fight Against*

[3] The government faults Dr. Shafa for referring to naltrexone as "a medically accepted [FDA] approved drug," but the very next paragraph of the consent form went on to add, "[n]altrexone has not been approved by the [FDA] for use in pellets." Trial Ex. 32 at 39. While Dr. Shafa, perhaps, could have been clearer, he conveyed the essence of the situation: that naltrexone is the active ingredient in certain approved medications to treat addiction, but the pellet implants were not FDA approved. Indeed, as the defense has previously noted, the relevant patients admitted in their trial testimony that they knew the pellets were not approved.

Opioid Addiction, (last visited Sept. 2, 2024).[4] In fact, a doctor at Columbia received a grant from the National Institutes of Health ("NIH") for a study of this treatment method. *See id.*; *see also* NIH, *Better Ways to Deliver Medications That Treat Addiction* (last visited Sept. 2, 2024) (discussing study with funding from NIH grant).[5] The presence of triamcinolone in the pellets similarly did not preclude them from being safe and effective. *See* Evgeny Krupitsky *et al*, *Randomized Trial of Long-Acting Sustained-Release Naltrexone Implant vs Oral Naltrexone or Placebo for Preventing Relapse to Opioid Dependence* (Sept. 2012) (article reflecting results of study involving implant containing naltrexone and "a small dose of triamcinolone acetonide . . . to prevent inflation," resulting in no serious adverse events).[6]

As the defense has pointed out, and the government does not dispute, Dr. Shafa's patients, including the specific patient relied on regarding this issue (Ms. Repetto), signed a consent form specifically stating that the duration of the implant would be "up to 10 months." Dkt. 250 at 14 (quoting Trial Ex. 32 at 39). The consent form went on to discuss possible risks and side effects, including "the possibility that the pellet will not be effective for the exact time listed" and even "the risk that the pellet will not work at all." Trial Ex. 32 at 40; *see also id.* at 42 ("Naltrexone[] will not work for some percentage of the population."). The form also noted that "implanting the pellet," which it explicitly stated was not an FDA approved manner of administering naltrexone, may "result in new side effects." Trial Ex. 32 at 40. Another form signed by Ms. Repetto stated,

[4] *Available at* https://columbiasurgery.org/news/naltrexone-implant-powerful-new-tool-fight-against-opioid-addiction

[5] *Available at* https://heal.nih.gov/news/stories/naltrexone-implant

[6] *Available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3614358/

"[p]sychotherapeutics (medications that work on the mind), like other medications . . . , are not perfected, they do not work for everybody, and may cause known and/or unknown side effects. Although their benefit can be life saving, . . . at times their side effects can be life threatening." *Id.* at 5.[7]

At the very least, the government's evidence regarding alleged misrepresentations to three specific patients cannot support a finding that Dr. Shafa caused a loss exceeding $650,000 to more than 120 patients. This is especially so when several of the very patients included in the loss calculation testified at trial that they received from Dr. Shafa the essence of what they bargained for. While some of these patients experienced complications, there is no medical procedure in the world that is risk free. Dr. Shafa told his patients this. *See* Trial Ex. 32 at 12 ("It has been explained to me that every treatment involves certain risks and possibilities of complications including death."). Dr. Shafa further informed patients, "the practice of Medicine and Surgery is not an exact science," and Dr. Shafa expressly made "no guarantees," because he could not, "as to the results of the procedure." *Id.* at 40. Dr. Shafa's patients came to see him in the throes of severe, and often life-threatening, opioid addiction. Serious intervention was required, even though it, of course, involved some measure of risk. One of the patients testified at trial that the treatment he paid Dr. Shafa for saved his life. *See* Feb. 5, 2024 Tr. at 158. Certainly, amounts paid by patients to receive such life-saving treatments should not be included (as they currently are) in the fraud loss calculation.

[7] The government makes much of the fact that this particular consent form referred the patient to "fda.gov" for questions, but the form was not specific to naltrexone and included other FDA approved medications that Dr. Shafa used in his practice, including Suboxone.

Kumar is readily distinguishable. There, the defendant oversaw call centers selling "generic versions" of medications, none of which were "approved by the FDA." 2024 WL 3755360, at *1. The call centers, however, told customers, among other false information, "that the drugs were approved by the FDA." *Id.* In these circumstances, it was reasonable for the court to conclude that all of the sales (of unapproved medications to customers told they were approved) were fraudulent. Here, by contrast, the evidence was uncontroverted that Dr. Shafa told patients the pellet implants were not approved. *See United States v. Andersen*, 45 F.3d 217, 221 (7th Cir. 1995) (finding insufficient proof of loss to customers where "the customers appear[ed] to have been well aware that the drugs they were purchasing were not approved by the FDA," and "[e]ven if . . . the customers were given some false information, the government present[ed] no evidence that that misinformation led to any quantifiable loss").

The application note relied upon by the government regarding a "special rule" applicable to "goods for which regulatory approval by a government agency was required but not obtained" is not included in the text of the guideline. Dkt. 251 at 14-15 (quoting U.S.S.G. § 2B1.1, n.3(F)(v)). Accordingly, to the extent the Court finds this language requires a calculation that exceeds the plain meaning of "loss," the Court must apply the terms of the guideline itself. *See United States v. Banks*, 55 F.4th 246, 258 (3d Cir. 2022) (finding that commentary inappropriately "expands the definition of 'loss'" to include "intended loss" and such commentary is therefore entitled to "no weight"). It is notable that, in responding to the Third Circuit's *Banks* opinion, the Sentencing Commission adopted an amendment to move some of the commentary, including the definition of

"loss" to encompass "intended loss," into the text. It did not, however, elect to so move the note relied upon by the government here.

Any alleged misrepresentations to customs, which the government features prominently in an unpersuasive attempt to avoid the acquitted conduct Amendment, are beside the point in the context of a purported loss calculation based on amounts paid by patients. Dr. Shafa's patients did not suffer a loss caused by any misrepresentations to customs. The loss resulting from such misrepresentations, if any, would be duties the defendant avoided paying as a result. The smuggling guideline, which again includes no fraud cross-reference, clearly contemplates this fact by tying offense level to tax loss. *See* U.S.S.G. § 2T3.1. The government has made no attempt to calculate the tax loss here.

Even assuming *arguendo*, and contrary to the foregoing, that any alleged fraud on customs is relevant in this context, the defense also respectfully submits that the government failed to prove that the shipment labels generated by Moran were intentionally fraudulent. As the Court knows from pre-trial litigation regarding this issue, Moran testified at the criminal trial of Lance Gooberman that "a customs official in Anchorage told [Moran's] practice manager that" plastic beads in plastic tubes was what the implants "should be labeled." Dkt. 164-1 at 62. The Court may consider this sworn testimony at sentencing, regardless of whether or not it was admissible at trial. *See* U.S.S.G. § 6A1.3(a).

III. OTHER ISSUES UNDER § 2B1.1

A similar error undermines the government's contention that the enhancement applies for an offense involving ten or more victims simply because "smuggled drugs were sold to at least 120 patients." Dkt. 251 at 17. The guideline defines "victim" as "any person who sustained any part of the actual loss." U.S.S.G. § 2B1.1 n.1. It is limited to ***fraud*** victims. For reasons set forth above, and in prior filings, the government has failed to prove that there were ten or more victims of any fraud by Dr. Shafa.

The government neglects to mention that its sole authority on this issue, *Sen*, involved clear and direct frauds on "at least 10 health care benefit program victims." 24 F. Supp. 3d at 745. While the court also mentioned the number of patients who had received the non-approved drug, in that case there was "a sign posted in the chemotherapy room reassuring patients that the practice used only FDA approved drugs." *Id.* Here, by contrast, there is no dispute that the patients were informed the pellets were not FDA approved.

The government position on this issue suffers from two additional obstacles. First, any alleged fraud on patients, even if proven, falls squarely within the acquitted conduct Amendment and therefore may not be considered to enhance Dr. Shafa's sentence. Second, the only guideline at issue that includes a fraud cross-reference is that applicable to misdemeanor misbranding, such that the statutory maximum one-year sentence caps the guideline range. *See* Dkt. 240 at 2-3. The Supreme Court's recent opinion in *Erlinger v. United States*, 144 S. Ct. 1840 (2024) is certainly not "irrelevant" on this latter point.

IV. NO AGGRAVATING ROLE ENHANCEMENT APPLIES.

The government's argument on this issue utterly fails to acknowledge that both Dr. Shafa and his co-defendant Nahid Tormosi were acquitted at trial on all counts that included Tormosi. Thus, the acquitted conduct Amendment should preclude application of this enhancement to Dr. Shafa. *See* Dkt. 238 at 7-9.

It is clear that none of the other potential "participants" that Dr. Shafa allegedly supervised were "criminally responsible for the commission of the offense," as required by the guideline. U.S.S.G. § 3B1.1 n.1. The government essentially concedes it cannot meet its burden on this point by stating that some (unspecified) individuals participated "wittingly, some not." Dkt. 251 at 21. An unwitting participant is not a "criminally responsible" participant for purposes of this guideline.

Independent of the acquitted conduct issue, neither the government nor the PSR points to any single criminal act by Tormosi directed by Dr. Shafa. There is nothing unlawful, much less criminal, about "schedul[ing] potential patients" or "collect[ing] payments," which are typical tasks performed by administrative personnel in any legitimate medical office. Dkt. 251 at 21. While the government also contends that Tormosi "helped obtain the misbranded drugs," *id.*, the only evidence included in the PSR on this point is Tormosi's receipt of a single email from Moran. *See* PSR ¶¶ 19b, 27b. This does not constitute a criminal act by Tormosi directed by Dr. Shafa.

In fact, the defense respectfully submits that Dr. Shafa is entitled to a ***minor*** role adjustment pursuant to U.S.S.G. § 3B1.2(b). There was only one other criminally responsible "participant" in the crimes of conviction: Wayne Moran. And Dr. Shafa was clearly "less culpable" than Moran in the smuggling. § 3B1.2 n.5. It was Moran, not Dr.

Shafa, who emailed about using the "plastic beads in . . . plastic tubes" description. Feb. 8, 2024 Tr. 48. And there was "no dispute" at trial that "Moran or one of his associates," not Dr. Shafa, created the allegedly false labels underlying the counts of conviction. *Id.* at 54. The government counters that, on one occasion, Dr. Shafa "used" the "false" "plastic beads in plastic tubes" description "when he sent implants to Moran." Dkt. 251 at 12. The evidence showed that Dr. Shafa was returning expired products to Moran. *See* Jan. 26, 2024 Tr. 137. The shipping label on page one of the relevant exhibit describes the contents as "Medical Device." Trial Ex. 12.1. Shipping labels generated by Moran, by contrast, used the "Plastic beads in plastic tubes" description. *See, e.g.*, Trial Ex. 3.1. While the commercial invoice on the second page bears the description "Plastic Beads in Plastic Tubes," Dr. Shafa, unlike Moran, truthfully disclosed that the products were also intended as medical devices. In any event, the government did not charge Dr. Shafa with the shipment of expired products, and it is undisputed that it was Moran or his associates who generated the allegedly false description for all charged transactions, making Moran the more culpable of the two participants.

V. NO ABUSE OF TRUST ENHANCEMENT APPLIES

The government does not explain how Dr. Shafa's position of trust or special skills as a physician "facilitated the commission or concealment" of any "offense," much less "significantly" so. U.S.S.G. § 3B1.3. Dr. Shafa stands convicted of unlawfully importing medical products, making international monetary transactions to facilitate such importation, and receiving the misbranded products in interstate commerce. Dr. Shafa could have just as easily committed these offenses without a medical license. Dr. Shafa was not charged, much less convicted, of performing surgeries "in dirty and unsafe

conditions." Dkt. 251 at 20. The other alleged conduct cited by the government, involving misrepresentations to patients, is acquitted conduct that may not be considered under the Amendment.

VI. ALTERNATIVE CALCULATION UNDER U.S.S.G. § 2S1.1

Because the base offense level under the money laundering guideline, U.S.S.G. § 2S1.1, is based on the "offense level for the underlying offense," the foregoing calculation errors by the government also inflate its calculation of an offense level of 24 under this guideline. There is no basis for applying § 2S1.1(a)(2)'s alternative calculation based on the amount of funds laundered because this subsection is inapplicable absent a showing (not even attempted by the government here) that the guideline level under subsection (a)(1) cannot be determined. *See* Dkt. 238 at 14-15.

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Respectfully submitted,
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Certificate of Service

I, Martin G. Weinberg, hereby certify that on this the 3rd day of September 2024, I caused a true copy of the foregoing document to be served upon all necessary parties to this matter via the Court's electronic filing system.

/s/ Martin G. Weinberg
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